

### **REMARKS**

In the Final Office Action dated September 19, 2008, the Examiner rejected claims 1, 2, 8, 11, 13, 15-25, 28, 29, 31-34, and 38-50 under 35 U.S.C § 103(a) as being unpatentable over U.S. Patent No. 6,293,321 to Shinmoto et al. ("Shinmoto") in view of U.S. Patent No. 4,738,668 to Bellotti et al. ("Bellotti '668"); rejected claim 12 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668 and further in view of U.S. Patent No. 4,882,496 to Bellotti et al. ("Bellotti '496"); and rejected claims 26, 27, and 30 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668 and further in view of U.S. Patent No. 4,655,753 to Bellotti et al. ("Bellotti '753").

By this Amendment, Applicant has amended claims 1, 29, and 33 and cancelled claims 2 and 34. Accordingly, claims 1, 7-33, and 38-50 are currently pending in this application. No new matter has been added by this Amendment.

### **REJECTIONS UNDER § 103(a)**

Applicant respectfully traverses the Examiner's rejection of claims 1, 2, 8, 11, 13, 15-25, 28, 29, 31-34, and 38-50 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668. Applicant submits that the cited references do not teach, disclose, or suggest all of the elements of amended independent claims 1, 29, and 33.

In Applicant's Request for Reconsideration After Final mailed December 19, 2008, Applicant submitted that Bellotti '668 does not disclose sterilization of the connection area before the container of spent dialysis solution is disconnected so that a clean environment is created during the disconnection of the dialysis container, as

required by the claimed invention, and as disclosed in paragraph [0014] on 2 of the published application. (Request for Reconsideration at 17.) In the Advisory Action, the Examiner contended that “Applicant further argues that Bellotti ‘668 does not disclose sterilization of the connection area before disconnection of the spent dialysis container. However, such a step is not clearly set forth in the pending claims.” (Advisory Action at 2.) Although Applicant does not necessarily agree with the Examiner, Applicant has amended claims 1, 29, and 33 to clarify the claims.

Accordingly, amended independent claim 1 recites, among other features, a “flow generator configured to supply said inward flow of gas at least during the connection . . . and a disconnection of the first connection portion and the second connection portion, thereby enabling both the connection and the disconnection of the first and second connection portions to be performed in a substantially sterile atmosphere.” (Emphasis added.) Similarly, amended independent claim 29 recites a “flow generator configured to supply said inward flow of gas at least during the connection . . . and a disconnection of the first connection portion and the second connection portion . . . enabling both the connection and the disconnection of the first and second connection portions to be performed in a substantially sterile atmosphere” (emphasis added), and amended independent claim 33 recites “providing an inward flow of gas into the inner space . . . at least during connecting . . . and disconnecting the first connection portion from the second connection portion . . . enabling both connecting and disconnecting of the first and second connection portions to be performed in a substantially sterile atmosphere.” (Emphasis added.) Accordingly, Applicant submits that neither Shinmoto nor Bellotti

'668 teaches, discloses, or suggests the limitations of independent claims 1, 29, and 33 as amended.

Applicant also maintains that Bellotti '668 does not disclose “a flow generator for providing said inward flow of gas through the channel, said flow generator configured to supply said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion” (emphasis added), as recited in independent claims 1 and 29. The Examiner contends that “since Bellotti teaches the use of a syringe, which may hold sterile gas for later use, Bellotti reasonably suggests that sterile gas may be flowed during various steps of the connection and disconnection process.” (Advisory Action at 2.) Applicant disagrees. Bellotti '668 discloses that “[t]he chlorine gas or other desired preferably gaseous sterilizing material may be added from an ampule, particularly an ampule in which pressure is generated to force the gas into the system when desired. *Alternatively*, a syringe, squeeze bulb, or the like may be used.” (Col. 4, lines 6-10, emphasis added.) Thus, Bellotti '668 discloses a syringe or a squeeze bulb as being a simple *replacement* or *alternative* to an ampule. In other words, using the squeeze bulb or syringe of Bellotti '668 as a simple *replacement* for the ampule actually teaches away from utilizing the syringe or squeeze bulb in a different manner than disclosed in the reference (as is suggested by the Examiner).

Accordingly, for at least all of the reasons discussed above, amended independent claims 1, 29, and 33 are allowable over the cited references. Thus, claims 8, 11, 13, 15-25, 28, 31, 32 and 38-50 are allowable over the cited references at least

due to their dependence from allowable independent claims 1, 29, or 33 and due to their additional recitations of patentable subject matter.

The Examiner also rejected claim 12 under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668 and further in view of Bellotti '496.

Bellotti '496 discloses an “[a]pparatus for disconnecting, sterilizing and making new tubing connection[s].” (Abstract.) The Examiner contends that Bellotti '496 discloses “a patient connector apparatus comprising a base 14 that holds connectors, enclosed by lid 12 in order to provide a sterile location for connecting the fluid lines (see FIG2, generally, column 4).” (Final Office Action at 5.) Bellotti '496 does not disclose a “flow generator configured to supply said inward flow of gas at least during the connection . . . and a disconnection of the first connection portion and the second connection portion, thereby enabling both the connection and the disconnection of the first and second connection portions to be performed in a substantially sterile atmosphere,” (emphasis added) as disclosed in amended independent claim 1. Thus, Bellotti '496 fails to cure the above-mentioned deficiencies of Shinmoto and Bellotti '668. Accordingly, claim 12 is allowable at least due to its dependence from allowable independent claim 1 and due to its additional recitations of patentable subject matter.

Claims 26, 27, and 30 were rejected under 35 U.S.C § 103(a) as being unpatentable over Shinmoto in view of Bellotti '668 and further in view of Bellotti '753. Bellotti '753 discloses “[a] device [that] automatically uncouples two connectors and forms a new coupling between one of the connectors and another connector in a aseptic manner, without touch contamination from the user.” (Abstract.) Shinmoto, Bellotti '668, and Bellotti '753 do not disclose a “flow generator configured to supply said

inward flow of gas at least during the connection . . . and a disconnection of the first connection portion and the second connection portion, thereby enabling both the connection and the disconnection of the first and second connection portions to be performed in a substantially sterile atmosphere," (emphasis added) as disclosed in amended independent claim 1. Thus, Applicant submits that Bellotti '753 fails to cure the above-mentioned deficiencies of Shinmoto and Bellotti '668. Accordingly, claims 26, 27, and 30 are allowable at least due to their dependence from allowable independent claim 1 and due to their additional recitations of patentable subject matter.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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